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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,048	05/21/1999	LUC DESGROSEILLERS	10875.77	7290

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EXAMINER	
SHUKLA, RAM R	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/316,048	DESGROSEILLERS ET AL.	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on th cov r she t with the corr spondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-8 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-8 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of the invention of group I, claims 4-8 and 24-29 drawn to a human or mouse Staufen nucleic acid sequence in Paper filed 8-8-03 is acknowledged.

2. Claims 4-8 are objected to because they encompass non-elected invention (C.elegans nucleic acids). Applicants are required to amend the claims to reflect the elected invention.

3. Claims 4-8 and 24-29 drawn to human or mouse Staufen nucleic acid sequences are instantly under consideration.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4-8 and 24-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO 1, 3, 5, 6, and 7, (ii) an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO 8, SEQ ID NO 10, SEQ ID NO 2, SEQ ID NO 4, amino acid residues 1-577 and 2-577 of SEQ ID NO 2, amino acid residues 2-487 of SEQ ID NO 8, and amino acids 2-496 of SEQ ID NO 4 and (iii) a nucleic acid complimentary to the full length nucleic acids of (i)-(ii), a recombinant vector comprising the isolated nucleic acid, a method of making a recombinant host cell comprising the isolated nucleic acid, a host comprising the nucleic acid, and a method of making the polypeptide encoded by the nucleic acid, does not reasonably provide enablement for a nucleic acid encoding proteins that have at least 95% identity to an isolated nucleic acid encoding the amino acid

sequence of SEQ ID NO 8, SEQ ID NO 10, SEQ ID NO 2, SEQ ID NO 4, amino acid residues 1-577 and 2-577 of SEQ ID NO 2, amino acid residues 2-487 of SEQ ID NO 8, and amino acids 2-496 of SEQ ID NO 4 or other recited embodiments for reasons of record set forth in the previous office action of 9-10-02. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 4 encompasses any nucleotides that have at least 95% sequence identity to nucleotide sequences that encode the proteins of SEQ ID NO 2, 4, 8, 10, AA 1-577 or 2-577 of SEQ ID NO 2, AA 2-496 of SEQ ID NO 4, AA 2-487 of SEQ ID NO 8. The specification does not teach how to make and use the broad scope of the claimed polynucleotides encompassed by the claimed invention and whether the proteins encoded by such nucleic acids will be functional. In particular, the specification does not teach as to altering of which 5% nucleotide sequences will result in a nucleotide sequence that encodes a functional protein. While figure 1 shows the sequence similarity between mouse and human sequence this figure does not provide any guidance as to which nucleotides to change. It is emphasized that the nucleic acids encompasses by the claimed invention will not only include the variants of the sequences listed above, they would also encompass the nucleotide sequences from other organisms, which meet the recited 95% sequence identity limitation. The specification does not provide any guidance how to make and use the nucleic acid molecules from other organisms. As noted in the previous office action, it is recognized in the prior art that the function of a protein depends on the sequence of its amino acids in a certain pattern, conformation of the protein due to the amino acid sequence, and the functional properties of the different parts of the protein. Furthermore, comparing the results in figure 1b and 1' in the specification indicates that the proteins of human, mouse, C.elegans and Drosophila are not related to the same extent of sequence identity. Since the sequence encompassed by the claimed nucleic acids will encompass nucleic acid from any organism, an artisan of skill will not know which sequences to alter to make a sequence that will meet the sequence identity requirements of the claimed

invention and will be functional. Alternatively, the specification does not teach how to use a nucleic acid that would encode a non-functional protein. Even if one had to use the claimed nucleotides as probes, a probe based on the claimed invention would not have resulted in finding a nucleic acid that would encode a protein that would have the function of the protein encoded by the claimed invention. As noted previously in the office action, Rudinger et al stated, "The significance of particular amino acids and sequences for different aspects of biological activity can not be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore an artisan would have required extensive experimentation to determine the amino acids that were conserved and changed one at a time to identify the conserved amino acids and such experimentation would have been undue.

Claims 4 and 24 recite sequences that hybridize to sequences of (a) to (h) of claim 2 or sequences of (a)-(f) of claim 24 under high stringent conditions. The claimed invention is not enabled because of the discussion above and further because base on an artisan's interpretation, high stringency condition may vary. While the specification discloses 65 degree Celsius as an example of the hybridization conditions, as instantly claimed any temperature or hybridization condition could be considered highly stringent. It is noted that claims encompass polynucleotide that will hybridize to sequences that have 95% sequence identity to a sequence that encodes an amino acid sequences which is not functional as discussed earlier and the specification does not teach an artisan how to use a nucleic acid that would hybridize to a nucleic acid that encoded a non-functional protein.

Therefore, in view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, one of ordinary skill in the art at the time of the invention would have required an undue amount of experimentation to make and use claimed polynucleotides commensurate with the scope of the claimed invention and therefore, limiting the scope of the claimed invention to (i) an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO 1, 3, 5, 6, and 7, (ii) an isolated nucleic acid

encoding the amino acid sequence of SEQ ID NO 8, SEQ ID NO 10, SEQ ID NO 2, SEQ ID NO 4, amino acid residues 1-577 and 2-577 of SEQ ID NO 2, amino acid residues 2-487 of SEQ ID NO 8, and amino acids 2-496 of SEQ ID NO 4 and (iii) a nucleic acid complimentary to the full length nucleic acids of (i)-(ii), a recombinant vector comprising the isolated nucleic acid, a method of making a recombinant host cell comprising the isolated nucleic acid, a host comprising the nucleic acid, and a method of making the polypeptide encoded by the nucleic acid is proper.

6. Claims 4 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

When the claims are analyzed in light of the specification, instant invention encompasses nucleic acid molecules comprising a polynucleotide sequence encodes a protein that is at least 95% identical to SEQ ID NO 4, 8, 10, AA 1-577 or 2-577 of SEQ ID NO 2, AA 2-496 of SEQ ID NO 4, AA 2-487 of SEQ ID NO 8 or any sequence that is complimentary to these sequences or a sequence that hybridizes to any of these sequences. The specification discloses only SEQ ID NO 1, 3, 5, 6, and 7 that encode a polypeptide disclosed in SEQ ID NO 2, 4, 8, and 10. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, SEQ ID Nos 1, 3, 5, and 7 are the only species whose complete structure is disclosed. The specification does not provide any disclosure as to what would have been the sequence structure of broad genus of sequences encompassed by the claimed invention. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only other identifying characteristic is the sequence identity of the claimed polynucleotides or hybridization to sequences. However,

these characteristics are not sufficient to identify the species of the claimed genuses and sub-genuses because there may be several sequences that will meet the sequence identity characteristic but may not be functional or have other characteristics. It is noted that the claim as instantly presented would encompass sequence from any species and the specification does not provide any disclosure whether these sequences from other species would have had same characteristics would have had additional characteristics or properties.

This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of cDNAs besides 1, 3, 5, 6, and 7 that encode a polypeptide disclosed in SEQ ID NO 2, 4, 8, and 10, at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to how the limitation " polynucleotide sequence being identical to a sequence" limits the scope of the claimed invention since the claim recites polynucleotides of certain SEQ ID NO.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 4 and 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al (Accession No. AA122533, Database EST, 2-17-97).

Marra et al teach a 522 bp nucleic acid sequence that has 99.8% best local sequence similarity with nt 2248-2770 of SEQ ID NO 7 and therefore would hybridize to SEQ ID NO 7 under stringent conditions.

Accordingly the invention of claims 4 and 24 are anticipated by Marra et al.

11. Claims 4 and 24 is rejected under 35 U.S.C. 102(a) as being anticipated by Banfi et al (Accession No. G30939, Database GenEmbl, 9-29-98; Nature Genetics 13:167-174, 1996).

Banfi et al teach a 385 bp nucleic acid sequence that has 99.2% sequence similarity with nt 2705-3089 of SEQ ID 1, 3069-3453 of SEQ ID NO 1, and 2911-3295 of SEQ ID NO 6 and therefore would hybridize to SEQ ID NO 1, and 6 under stringent conditions.

Accordingly the invention of claim 4 and 24 are anticipated by Banfi et al.

12. No claim is allowed.

13. The nucleic acid sequences of 1, 3, 5, 6, and 7 that encode a polypeptide disclosed in SEQ ID NO 2, 4, 8, and 10 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday

from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632